March 5, 2025

Well Lead Medical Co., Ltd.
Jimmy Chen
Regulatory Affairs Specialist
No.47, Guomao Avenue South, Hualong, Panyu
Guangzhou, 511434
CHINA

Re: K241734
Trade/Device Name: Wellead® Hydrophilic Intermittent Catheter Ready to Use;
Wellead® Hydrophilic Intermittent Catheter Compact
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: January 18, 2025
Received: February 3, 2025

Dear Jimmy Chen:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241734

Device Name

Wellead® Hydrophilic Intermittent Catheter Ready to Use, Wellead® Hydrophilic Intermittent Catheter Compact

Indications for Use *(Describe)*

Hydrophilic Intermittent Catheter is used to empty the bladder for patients with urinary retention or incomplete bladder emptying.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Submitter Identification

Submitter Name: Well Lead Medical CO., LTD.
Submitter Address: No.47, Guomao Avenue South, Hualong, Panyu, Guangzhou, China 511434
Establishment Registration Number: 3010400865
Tel: 86 2084758878-8628

Contact Person (including title):
Ms. Jenny Zhu (RA Supervisor); Mr. Jimmy Chen (RA Specialist);
E-mail: jenny_zhu@welllead.com.cn; chenjinyi@welllead.com.cn;

2. Device Identification

Type of 510(k) submission: Traditional

Common Name: Urethral Catheter

Trade Name: Wellead® Hydrophilic Intermittent Catheter Ready to Use
Wellead® Hydrophilic Intermittent Catheter Compact

Device: Catheter, urethral

Regulation Name: Urological catheter and accessories

Regulation Medical Specialty: Gastroenterology/Urology

Review Panel: Gastroenterology/Urology

Product Code: EZD

Regulation Number: 21 CFR 876.5130

Regulation Class: Class II

3. Predicate Device Information

	Predicate Device
Sponsor	Coloplast Corp
Device Name	SpeediCath Standard
510(k) Number	K180258
Product Code	GBM
Regulation Number	21 CFR 876.5130
Regulation Class	Class II

	Predicate Device
Sponsor	Coloplast Corp
Device Name	SpeediCath Compact SpeediCath Compact Plus
510(k) Number	K203637
Product Code	EZD
Regulation Number	21 CFR 876.5130
Regulation Class	Class II

The predicate devices have not been subject of a design-related recall.

4. Device Description

Hydrophilic intermittent catheter is a sterile, single use hollow tube inserted into the bladder to drain the urine at regular intervals. The catheter also contains a Polyvinyl Pyrrolidone hydrophilic-coating and is sterilized by irradiation. The product can be used on patients who need intermittent urine drainage. The Hydrophilic intermittent catheter is available for use in professional medical facilities and home environments.

The Hydrophilic Intermittent Catheter Ready to Use is placed in a wetting liquid, packed and sealed in a foil pouch and sterilized.

The Hydrophilic Intermittent Catheter Compact is placed in a wetting liquid inside the container, which together with screw cap, connector and plug make up the primary packaging and the sterile barrier.

The Hydrophilic Intermittent Catheter Ready to Use is available in three configurations:

- Ready to use Female (8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr)
- Ready to use Standard (8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr)
- Ready to use Tiemann (10Fr, 12Fr, 14Fr, 16Fr, 18Fr)

The Hydrophilic Intermittent Catheter Compact is available in one configuration (8Fr, 10Fr, 12Fr, 14Fr, 16Fr).

5. Indications for Use

Hydrophilic Intermittent Catheter is used to empty the bladder for patients with urinary retention or incomplete bladder emptying.

6. Summary of Non-clinical Performance Testing

Hydrophilic Intermittent Catheter has been evaluated for safety and performance by lab bench testing as follows:

Non -clinical bench testing:

- ISO 20696:2018, Sterile urethral catheters for single use
- ASTM F623-19, Standard performance specification for Foley Catheter
- pH testing
- Osmolarity testing
- Surface drying time of coating

Packaging:

- ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886 Standard Test Method for Determining integrity of Seals for Flexible Packaging by Visual inspection

Aging:

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Biocompatibility:

- ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016 Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation;
- ISO 10993-17:2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents;
- ISO 10993-18: 2020, Biological Evaluation of Medical Devices -Part 18: Chemical characterization of medical device materials within a risk management process

7. Comparison of Technological Characteristics

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Device Name and Model	Hydrophilic Intermittent Catheter Ready to Use Hydrophilic Intermittent Catheter Compact	SpeediCath Standard	SpeediCath Compact SpeediCath Compact Plus	N/A
510 (K) Number	K241734	K180258	K203637	N/A
Regulation number	21 CFR 876.5130	21 CFR 876.5130	21 CFR 876.5130	SE
Regulation description	Urological catheter and accessories	Urological catheter and accessories	Urological catheter and accessories	SE
Product code	EZD	GBM	EZD	SE
Class	Class II	Class II	Class II	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Indication for Use	Hydrophilic intermittent catheter is used to empty the bladder for patients with urinary retention or incomplete bladder emptying.	Urinary catheter for intermittent use. The catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing the urine to drain.	SpeediCath Compact and SpeediCath Compact Plus is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The product is indicated for female patients only (adults and children of and above the age of 2 years). Choice of model and size of the catheter for the individual patient is made upon recommendation by the local health care professional.	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Prescription use	Prescription use	Prescription use	Prescription use	SE
Sterility	Sterilized – Single use	Sterilized – Single use	Sterilized – Single use	SE
Sterilization Method	Radiation	Radiation	Radiation	SE
Use	The catheter is inserted into the urethra to reach the bladder allowing the urine to drain.	The catheter is inserted into the urethra to reach the bladder allowing the urine to drain.	The catheter is inserted into the urethra to reach the bladder allowing the urine to drain.	SE
Catheter Material	Polyurethane	Polyurethane	Polyurethane	SE
Packaging	The Hydrophilic Intermittent Catheter Ready to Use is placed in a wetting liquid, packed and sealed in a foil pouch and sterilized. The Hydrophilic Intermittent Catheter Compact is placed in	The catheter is placed in a swelling media, packed and sealed in a foil pouch and sterilized.	The catheter is hydrophilic coated and placed in a sterile solution (swelling medium) inside the inner tube, which together with a handle and plug make up the primary packaging and the sterile barrier.	SE Note 2

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	a wetting liquid inside the container, which together with screw cap, connector and plug make up the primary packaging and the sterile barrier.			
Catheter OD (Fr Size)	Ready to use Standard: 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr Ready to use Female: 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr Ready to use Tiemann: 10Fr, 12Fr, 14Fr, 16Fr, 18Fr Compact Female: 8Fr, 10Fr, 12Fr, 14Fr, 16Fr	Male: 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr Female: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr Tiemann: 10Fr, 12Fr, 14Fr, 16Fr Pediatric: 6Fr, 8Fr, 10Fr Boys: 6Fr, 8Fr, 10Fr, 12Fr	SpeediCath Compact is available in size FR/CH 8-14. SpeediCath Compact Plus is available in FR/CH 10-14.	SE Note 3

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Biocompatibility	Cytotoxicity Test-ISO 10993-5; Intracutaneous Reactivity Test-ISO 10993-23; Sensitization Test-ISO 10993-10; Pyrogen Test-ISO 10993-11; Implantation Test-ISO 10993-6. Chemical characterization-ISO 10993-18.	Biocompatibility testing according to ISO 10993-1:2009 and FDA Guidance "Use of International Standard ISO 10993-1" (2016) was completed.	Biocompatibility testing (cytotoxicity, irritation, sensitivity, pyrogenicity and chemical characterization) according to ISO 10993-1:2009 and FDA Guidance "Use of International Standard ISO 10993-1" (2016) was completed.	SE Note 4
Accelerated Aged shelf life Test	Complies with ASTM F1980-16.	Complies with ASTM F1980-16.	Complies with ASTM F1980-16.	SE Note 5
Sterilization	Complies with ISO 11137-11137-1 and ISO 11137-2.	Complies with ISO 11137-11137-1 and ISO 11137-2.	Sterilization dose setting according to ISO 11137-1:2015 and ISO/TS 13004:2013	SE Note 6
Hydrophilic Coating	PVP	PVP	PVP	SE

8. Comparison in Detail(s):

Note 1:

Although the specific language in the indication for use statement of the subject device is different from the predicate device, both have the same intended use applications and environment. Therefore, the subject device and predicate device have the same intended use.

Note 2:

The catheter material and packaging of the subject device and the predicate device are same. The second predicate device was used to justify the packaging of Compact Type of the subject device.

Note 3:

The outer diameters of the subject device and the predicate device are within the same range.

Note 4:

Both the subject device and the predicate device have undergone biocompatibility testing based on ISO 10993-1:2009 and FDA guidelines, showing that they are substantially equivalent.

Note 5:

Accelerated aging test of subject device and predicate device are in compliance with ASTM F1980-16.

Note 6:

The sterilization dose confirmation of subject equipment and predicate equipment is completed in accordance with ISO 11137-1.

9. Final Conclusion:

The technological characteristics, features, specifications, performance testing and indication for use of the Hydrophilic Intermittent Catheter support that the subject device is substantially equivalent to the predicate devices cited above.

10. Date of the summary prepared: March 5, 2025.